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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/601,785	06/27/00	XU	J 210121.427C1

EXAMINER

HM12/0925

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ART UNIT	PAPER NUMBER
1655	9

DATE MAILED: 09/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/605,783	Applicant(s) XU ET AL.	
	Examiner Janell Taylor Cleveland	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-63 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-63 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, 12-15, 23-24, and 25-28, drawn to a polypeptide, classified in class 530, subclass 350.

II. Claims 4-10, 16, and 58-60, drawn to a polynucleotide, classified in class 435, subclass 6.

III. Claims 11 and 54-57, drawn to antibodies and kits thereof, classified in class 530, subclass 387.1.

IV. Claims 17-20 and 21-23, drawn to a pharmaceutical composition, classified in class 424, subclass 184.1.

V. Claims 29-31, drawn to a method of inhibiting development of cancer by administering to a patient an antigen-presenting cell, classified in class 514, subclass 2.

VI. Claims 32-34, drawn to a method of removing tumor cells, classified in class 514, subclass 1.

VII. Claims 35-37, drawn to methods of stimulating and/or expanding T-cells, classified in class 424, subclass 184.1.

VIII. Claims 38-39, drawn to methods of inhibiting cancer comprising incubating CD4+ and CD8+ and T-cells, classified in class 424, subclass 184/1.

IX. Claims 40-53, drawn to a method for determining the presence or absence of cancer and monitoring the progression of cancer, classified in class 435, subclass 4.

The inventions are distinct, each from the other because of the following reasons:

1. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a nucleic acid and a protein, which have different functions, i.e., the nucleic acid codes for protein and the protein is used for various purposes in the cell. The nucleic acid is capable of functioning to code for a peptide without the peptide being present, and can be used by the practitioner to create probes, primers, and for diagnostic purposes without the presence of the peptide. Furthermore, the peptide is capable of functioning without the nucleic acid being present in the cell, as well as being useful to the practitioner.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to nucleic acids and proteins; and antibodies. Antibodies have different functions than proteins and nucleic acids, i.e., the antibody attaches to the protein, often disabling it from functioning, and the protein is useful for carrying out various cellular functions. The protein and the nucleic acid are capable of functioning in the cell without the antibody being present, and can be used

by the practitioner to create enzymes, or for diagnostic testing, or in the case of nucleic acids, to form probes or primers. Furthermore, the peptide is capable of functioning without the antibody being present in the cell, in fact, the protein usually cannot function when the antibody is present.

2. .Inventions I-III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a polypeptide, a polynucleotide, and an antibody. The pharmaceutical composition has a different function than the rest, as it is specifically designed to act on the body. The nucleic acids may function differently as probes or primers, and the proteins may function on the cellular level or may be used in differential expression assays. The antibodies may be used in ELISA assays.

3. Inventions I-IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to polynucleotides, polypeptides, antibodies, and pharmaceutical carriers, and the method of inhibiting the development of cancer. The method claims are substantially different than the product claims because they have different functions as well as different effects. The method claims inhibit the development of cancer, while the product claims are merely chemical compositions that function in the cell. Furthermore, the method claims contain steps

which are not required to obtain the products and the method steps do not require each product to inhibit cancer.

4. Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods for inhibiting development of cancer and methods of removing tumor cells. These methods have different modes of operation, as one actually removes the tumor cell from the body, and the other inhibits the development of the tumor at all.

5. Inventions VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods of removing tumor cells and methods of stimulating and/or expanding T-cells. These methods have different steps, and therefore different modes of operation. Furthermore, they have different functions, as one removes tumor cells while the other stimulates T-cells.

6. Inventions VII and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, as one stimulates and/or expands the T-cell population while the other inhibits cancer comprising incubating CD4 and CD8 cells. These have materially different method

steps which lead to different outcomes, as one increases the amount of T-cells while the other inhibits cancer.

7. Inventions VIII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods of inhibiting cancer and methods of determining the presence or absence of cancer and monitoring its progression. These have materially different method steps and one method inhibits cancer, as the final outcome, or effect, while the other monitors its progression or detects for its presence, where the final outcome of the method steps is not a form of treatment. These are therefore considered to be unrelated.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janell Taylor Cleveland whose telephone number is 703-305-0273. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on 703-308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-8724 for regular communications and 703-308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janell Taylor Cleveland
Examiner
Art Unit 1655

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600
9/11/01

September 20, 2001